

12 HOUR NASAL DECONGESTANT- pseudoephedrine hydrochloride tablet, film coated, extended release
CVS Pharmacy

CVS Pharmacy, Inc. 12 Hour Nasal Decongestant Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 120 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product

do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

adults and children 12 years and over	<ul style="list-style-type: none">• take 1 tablet every 12 hours• do not take more than 2 tablets in 24 hours
children under 12 years	do not use this product in children under 12 years of age

Other information

- each tablet contains: calcium 45 mg
- store at 20° - 25°C (68° - 77°F) in a dry place
- protect from light
- do not use if blister unit is broken or torn
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP Drug Release Test 3

Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Sudafed® 12 Hour Caplets

Non-Drowsy – Sinus

12 Hour Nasal Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 120 mg

LONG-ACTING NASAL DECONGESTANT

MAXIMUM STRENGTH

PSEUDOEPHEDRINE HCl

Sinus pressure

Congestion

12 HOUR

20 COATED CAPLETS*

*Capsule-Shaped tablets, 120 mg EACH

Actual Size

Non-Drowsy - Sinus

12 Hour Nasal Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 120 mg
LONG-ACTING NASAL DECONGESTANT

U.S. Patent No. 5,895,663



Compare to the active ingredient
in Sudafed® 12 Hour Caplets†

NDC 59779-703-60

Non-Drowsy - Sinus

12 Hour Nasal Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE
EXTENDED-RELEASE TABLETS, 120 mg
LONG-ACTING NASAL DECONGESTANT

MAXIMUM STRENGTH

PSEUDOEPHEDRINE HCl

- Sinus pressure
- Congestion



20 COATED CAPLETS*

*Capsule-Shaped tablets, 120 mg EACH



Actual Size


OPEN OTHER END

CONVENIENT RECLOSING TAB

†This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc., distributor of Sudafed® 12 Hour Caplets.

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V-16430





Drug Facts

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Drug Facts (continued)

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12 HOUR NASAL DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-703
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	L054	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-703-60	20 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59779-703-52	10 in 1 CARTON		
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA075153		12/01/1999	

Labeler - CVS Pharmacy (062312574)